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(54) **CHROMATOGRAPHY EQUIPMENT CHARACTERIZATION**

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See application file for complete search history.

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(57) **ABSTRACT**

Herein is reported a method for determining whether a re-usable chromatography column packing, which is used at least for the second time in a purification step of a purification of a polypeptide, has reduced separation efficacy in said purification step of said purification of said polypeptide, comprising the following steps: a) identifying and determining the experimental data of an inert change of at least one physicochemical parameter of a mobile phase passing through said re-usable chromatography column packing, b) determining the parameters of a function of formula I by fitting the experimental data of the inert change of the physicochemical parameter of the at least second use, c) determining the difference between the experimental data of the inert change of the physicochemical parameter of the at least second use and the function of formula I with the parameters determined in step b), d) calculating the difference between the maximum value and the minimum value of the difference determined in step c) and normalizing said difference, e) determining reduced separation efficacy of said re-usable chromatography column packing when the absolute value of the difference calculated in step d) is more than 0.1.

14 Claims, 9 Drawing Sheets